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Applicants:	Nguyen et al.	
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For :	VAPORIZER	

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APPEAL BRIEF

I. Real Party in Interest

The present application is assigned to Ethicon, Inc., a wholly owned subsidiary of Johnson & Johnson.

II. Related Appeals and Interferences

There are no related appeals or interferences.

III. Status of the Claims

The case contains 20, each of which are pending in the application and form the basis for this appeal. Each of these claims stands rejected.

IV. Status of Amendments

No amendments have been filed after the issuance of the Final Office Action.

V. Summary of the Claimed Subject Matter

The claimed invention defines a vaporizer 20 for vaporizing a sterilant 12 from its liquid phase in a vapor phase sterilization system 10 having a pressure below atmospheric pressure, said vaporizer comprising: an inlet 32 whereby to receive the sterilant in its liquid phase; an outlet 42 whereby to discharge the sterilant in its vapor phase; a circuitous path 34 between the inlet and the outlet whereby to collect non-vaporizable ingredients 40 of the sterilant; and a flow restriction 128 between the circuitous path and the outlet. (FIGS. 1 and 8, Spec. page 7, line 26 to page 8, line 11 and page 11, lines 23 to 25)

A vaporizer 20 for vaporizing a sterilant 12 from its liquid phase in a vapor phase sterilization system 10 having a pressure below atmospheric pressure, said vaporizer comprising: an inlet 32 whereby to receive the sterilant in its liquid phase; an outlet 42

whereby to discharge the sterilant in its vapor phase; a circuitous path 34 between the inlet and the outlet whereby to collect non-vaporizable ingredients 40 of the sterilant; a flow restriction 128 between the circuitous path and the outlet; and wherein the flow restriction comprises an orifice 128 having a cross-sectional area no greater than 44.1% of a cross-sectional area of the circuitous path immediately upstream of the orifice. (FIGS. 1 and 8, Spec. page 7, line 26 to page 8, line 11; page 11, lines 23 to 25 and page 4 lines 23 to 25)

A method of providing a vapor phase sterilant 12 to a sterilization chamber 22 comprises the steps of: creating temperature and pressure conditions within a vaporizer 20 sufficient to vaporize the sterilant said pressure condition comprising a pressure below atmospheric pressure; admitting the sterilant, in its liquid phase, into the vaporizer and vaporizing the sterilant; admitting no carrier gas into the vaporizer; passing the sterilant through a circuitous path 34 and collecting non-vaporizable components 40 of the sterilant on surfaces 38 forming the circuitous path; then passing the sterilant, in its vapor phase, through a flow restriction 128; and passing the sterilant, in its vapor phase, out of the vaporizer. (FIGS. 1 and 8, Spec. page 5 lines 1 to 14 and page 7, line 26 to page 8, line 11)

A method of providing a vapor phase sterilant 12 to a sterilization chamber 22 comprising the steps of: creating temperature and pressure conditions within a vaporizer 20 sufficient to vaporize the sterilant; admitting the sterilant, in its liquid phase, into the vaporizer and vaporizing the sterilant; passing the sterilant through a circuitous path 34 and collecting non-vaporizable components 40 of the sterilant on surfaces 38 forming the circuitous path; then passing the sterilant, in its vapor phase, through a flow restriction 128; passing the sterilant, in its vapor phase, out of the vaporizer; and wherein the step of passing the sterilant through the circuitous path comprises passing the sterilant through an orifice 128 having a cross-sectional area no greater than 44.1% of a cross-sectional area of the circuitous path immediately upstream of the orifice. (FIGS. 1 and 8, Spec. page 5 lines 1 to 14; page 4, lines 23 to 25 and page 7, line 26 to page 8, line 11)

A method of providing a vapor phase sterilant 12 to a sterilization chamber 22 comprising the steps of: creating temperature and pressure conditions within a vaporizer 20

sufficient to vaporize the sterilant; admitting the sterilant, in its liquid phase, into the vaporizer and vaporizing the sterilant; passing the sterilant through a circuitous path 34 and collecting non-vaporizable components 40 of the sterilant on surfaces 38 forming the circuitous path; then passing the sterilant, in its vapor phase, through a flow restriction 128; passing the sterilant, in its vapor phase, out of the vaporizer; and wherein at least 75% of the non-vaporizable components are removed from the sterilant prior to the step of passing the sterilant out of the vaporizer. (FIGS. 1 and 8, Spec. page 5 lines 1 to 23 and page 7, line 26 to page 8, line 11)

In one aspect of the invention the circuitous path comprises at least one portion 118 in which an effective cross-sectional area of the portion increases by at least 89% thereby decreasing the speed of the sterilant passing therethrough. (FIG. 6, Spec. page 10, line 22 to page 11, line 3, page 4, lines 16 to 20)

Preferably, wherein the flow restriction 128 can retain the vapor within the vaporizer for at least 17 milliseconds, and more preferably for at least 26 milliseconds. (Spec. page 4, lines 26 to 29).

VI. Grounds of Rejection to be Reviewed on Appeal

A. The rejection of claims 1 to 3 and 6 under 35 U.S.C. §102(b) over Hatanaka et al. (EP 0 321 908).

B. The rejection of claims 4, 5, 7 and 8 under 35 U.S.C. §103(a) over Hatanaka et al.

C. The rejection of claims 9 to 12, 14 to 16, 19 and 20 under 35 U.S.C. §103(a) over the Cummings et al. US Patent No. 4,744,951 and Hatanaka.

D. The rejection of claims 13, 17 and 18 under 35 U.S.C. §103(a) over Hatanaka et al in view of the Hatanaka et al. US Patent No. 4,797,255.

E. The rejection of claims 1 to 8, 13, 17 and 18 under 35 U.S.C. §103(a) over Hatanaka et al. and Liebold (DE 2639301).

F. The rejection of claims 9 to 12, 14, 16, 19 and 20 under 35 U.S.C. §103(a) over the Cummings et al. U.S. Patent No. 4,744,951, Hatanaka and Leibold.

G. The rejection of claim 15 under 35 U.S.C. §103(a) over Cummings et al., Hatanaka, Leibold and the Feasey et al. US Patent No. 5,130,053.

VII. Arguments

A. The rejection of claims 1 to 3 and 6 under 35 U.S.C. §102(b) over Hatanaka et al. (EP 0 321 908).

The Examiner has rejected claims 1 to 3 and 6 under 35 U.S.C. §102(b) over Hatanaka et al. ('908) Applicants submit that Hatanaka et al. lacks all of the features of these claims and therefore fails to anticipate the claimed invention. Specifically, claim 1 defines a vaporizer for vaporizing a sterilant from its liquid phase in a vapor phase sterilization system having a pressure below atmospheric pressure. Hatanaka et al. does not describe or teach operation below atmospheric pressure. Accordingly, it cannot anticipate claim 1 or the remaining claims which depend therefrom. Further, claim 1 defines a flow restriction, which the Hatanaka et al. reference lacks and which the Examiner has admitted that it lacks (see the Final Office action page 13, last paragraph).

B. The rejection of claims 4, 5, 7 and 8 under 35 U.S.C. §103(a) over Hatanaka et al.

Hatanaka et al. fails to teach operation below atmospheric pressure and fails to teach a flow restriction. Furthermore, it would not be obvious to one of skill in the art to so modify Hatanaka et al. as it operates under a fundamentally different principal, that of entertaining the vaporized sterilant in a carrier gas which is passed through the vaporizer. Accordingly, Applicants submit that Hatanaka et al. fails to make obvious the claimed invention.

Claim 4

Claim 4 defines at least one portion in which an effective cross-sectional area of the portion increases by at least 89% whereby to decrease the speed of the sterilant passing therethrough. The Examiner points to the casing 7 and the tube 10, noting the larger diameter of 7 with respect to 10, at least 70% according to the Examiner, although the relevance of the 70% figure is left unexplained, 70% being less than 89%. Unfortunately, given the direction of flow, the Examiner has identified a decreasing, not an increasing, cross-sectional area. The Examiner has failed to establish a prima facie case of obviousness.

Claim 5

Claim 5 defines the flow restriction as comprising an orifice having a cross-sectional area no greater than 44.1% of a cross-sectional area of the circuitous path immediately upstream of the orifice. The Hatanaka et al. reference lacks an orifice. The Examiner describes an "orifice space," whatever that is. It certainly is not an orifice. The Hatanaka et al. reference similarly lacks teaching relevant to the cross-sectional area of the orifice being no greater than 44.1% of the cross-sectional area of the circuitous path immediately upstream of the orifice. The Examiner's arguments about good mixing and residence time are unsupported by the reference. Hatanaka et al. provide no discussion of either proper mixing or residence time and the sole discussion of density relates to how the hydrogen peroxide is evaporated, not how it mixes with the carrier gas.

Claim 7

Claim 7 defines residency of the vapor within the vaporizer as being at least 17 milliseconds. Hatanaka et al. fail to teach this specific figure and fail to even discuss residency time. Whether or not the device of Hatanaka et el. is "intrinsically capable" of achieving the limitation of the claim through tweaking is irrelevant to establishing a prima facie case of obviousness, only what the reference actually teaches is relevant and this reference fails to teach the limitation of claim 7.

Claim 8

Claim 8 defines residency of the vapor within the vaporizer as being at least 28 milliseconds. Hatanaka et al. fail to teach or suggest this limitation.

C. The rejection of claims 9 to 12, 14 to 16, 19 and 20 under 35 U.S.C. §103(a) over the Cummings et al. US Patent No. 4,744,951 and Hatanaka.

There is no suggestion for making the alleged combination and even if made it would fail to reach the claimed invention. The Hatanaka and Cummings processes operate under fundamentally different conditions. Cummings et al. inject liquid sterilant into a vacuum with no carrier gas whereas Hatanaka et al. inject sterilant into a flowing carrier gas. One of ordinary skill in the art would not look to Hatanaka and its carrier gas type operation to modify the vacuum process of Cummings et al. The Examiner states that it would have been obvious to add the path of Hatanaka et al. to Cummings "since such a path results in a gas having a uniform density for improved surface sterilization (col. 4, lines 39-40) by preventing the disinfectant gas from forming into large drop (col. 4, lines 9-13)." Hatanaka et al. make no teaching of the path providing uniform density or of the gas forming a large drop. There is no large drop of gas. The translation is awkward which has confused the Examiner. The drop being described is one which might form if enough droplets carry through and then drop back onto the heated vaporizing surface. Uniform density as used in the reference refers to uniform vaporization of the hydrogen peroxide without having some portion avoid vaporization and then fall back and vaporize along with the then incoming hydrogen peroxide to produce a sudden increase in the amount of hydrogen peroxide gas in the carrier gas. The motivation for combining the references proposed by the Examiner is lacking from the references.

Furthermore, even if the alleged combination were made, it would not reach the claimed invention. Claim 9 includes the step of passing the sterilant in its vapor phase through a flow restriction. There is no flow restriction. Cummings et al. shows a block diagram of two chambers with a valved passage therebetween and the Examiner attempts to describe flow restriction status to the passage. This is unsupported in the specification and is merely a figment of the Examiner's imagination. The reference is clearly not drawn to scale. Neither is there teaching of restricting the flow. That teaching comes only from Applicants' specification and the Examiner is merely recreating the invention using hindsight.

Claim 12

Claim 12 refines the step of passing the sterilant through a circuitous path to include passing the sterilant through at least one portion in which an effective cross-sectional area of the portion increases by at least 89% thereby decreasing the speed of the sterilant passing therethrough. Hatanaka et al. lack this feature and the rejection of claim 12 lacks fails to point out where such feature lies in the reference. The Examiner has failed to establish a prima facie case of obviousness.

Claims 19 and 20

Claims 19 and 20 defines the sterilant as remaining within the vaporizer for at least 17 milliseconds, respectively. Hatanaka et al. fail to teach these specific figures and fail to even discuss residency time. Whether or not the device of Hatanaka et el. is "intrinsically capable" of achieving the limitation of the claim through tweaking is irrelevant to establishing a prima facie case of obviousness; only what the reference actually teaches is relevant and this reference fails to teach the limitation of either claim 19 or 20.

D. The rejection of claims 13, 17 and 18 under 35 U.S.C. §103(a) over Hatanaka et al ('908)in view of the Hatanaka et al. US Patent No. 4,797,255.

Each Hatanaka et al. fails to teach operation below atmospheric pressure and fails to teach a flow restriction. Furthermore, it would not be obvious to one of skill in the art to so modify Hatanaka et al. as it operates under a fundamentally different principal, that of entertaining the vaporized sterilant in a carrier gas which is passed through the vaporizer. Accordingly, Hatanaka et al. fail to make obvious the claimed invention.

Claim 13

Claim 13 defines that the step of passing the sterilant through the circuitous path comprises passing the sterilant through an orifice having a cross-sectional area no greater than 44.1% of a cross-sectional area of the circuitous path immediately upstream of the orifice. Neither Hatanaka et al. reference contains an orifice much less one meeting the cross-sectional area limitation.

Claim 17 and 18

Claim 17 defines that at least 75% of the non-vaporizable components are removed from the sterilant prior to the step of passing the sterilant out of the vaporizer and claim 18 provides that substantially all of the non-vaporizable components are removed. Neither reference provides teachings with respect to non-vaporizable components. They are concerned with droplets of peroxide which are vaporizable.

E. The rejection of claims 1 to 8, 13, 17 and 18 under 35 U.S.C. §103(a) over Hatanaka et al. and Liebold (DE 2639301).

There is no suggestion for making the alleged combination. Leibold discloses an evaporator for producing ethylene oxide and other toxic vapors and which comprises a vessel containing heated liquid into which is immersed a coiled tube. The vapors are produced in the coiled tube and a throttling device 7 limits the flow of these vapors so that too much does not flow at once and the vaporizer can run in continuous rather than batch mode.

Hatanaka et al. heat small quantities of hydrogen peroxide in a flow of carrier gas, send it through a baffle and then send it off to condense upon a surface to perform sterilization of that surface. Hatanaka et al. do not disclose a flow restriction between the baffle and the outlet.

One of skill in the art would not be motivated to combine the teachings of Leibold with those of Hatanaka et al. Leibold lacks a good method for controlling the rate of evaporation in the tube and so includes a flow restriction to prevent surges. The arrangement of Hatanaka et al. requires no such restriction as the evaporation is easily controlled by how fast drops of hydrogen peroxide are fed through the nozzle 20. No throttle would be necessary to prevent surges and would be contraindicated as it would add an unnecessary pressure drop into the system thus reducing energy efficiency. The Examiner asserts that adding the throttle of Leibold to Hatanaka et al. would allow the apparatus of Hatanaka et al. "to be used continuously instead of only intermittently, in a controlled manner without danger to the surrounding and personnel."

As can be seen, such is not necessary when the rate is controlled by the rate of drops coming out of the nozzle. Hatanaka et al. can be operated continuously without any flow restriction.

This is especially true given the use of a carrier gas. In such use one of skill in the art would want to promote good flow so as to not inhibit contact of the sterilant to the items being sterilized. Further, a flow restriction may slightly increase the danger rather than decrease it as it could cause a pressure back-up pushing the atmosphere upstream of the flow restriction closer to an explosive state. In any event, it is not needed and one of skill in the art would not be motivated to make the alleged combination.

Claim 4

Claim 4 defines at least one portion in which an effective cross-sectional area of the portion increases by at least 89% whereby to decrease the speed of the sterilant passing therethrough. The Examiner points to the casing 7 and the tube 10, noting the larger diameter of 7 with respect to 10, at least 70% according to the Examiner, although the relevance of the 70% figure is left unexplained, 70% being less than 89%. Unfortunately, given the direction of flow, the Examiner has identified a decreasing, not an increasing, cross-sectional area. The Examiner has failed to establish a prima facie case of obviousness.

Claim 5

Claim 5 defines the flow restriction as comprising an orifice having a cross-sectional area no greater than 44.1% of a cross-sectional area of the circuitous path immediately upstream of the orifice. The Hatanaka et al. reference lacks such an orifice as the Examiner admits. The Examiner asserts that the cross-sectional area of the flow restriction in Liebold is no more than about 25% of the cross-sectional area of the helical tubing. What is the basis for such assertion? The Examiner has failed to support this. Further, the Examiner's arguments about good mixing and residence time are unsupported by the reference. Hatanaka et al. provide no discussion of either proper mixing or residence time and the sole discussion of density relates to how the hydrogen peroxide is evaporated, not how it mixes with the carrier gas.

Claim 7

Claim 7 defines residency of the vapor within the vaporizer as being at least 17 milliseconds. Hatanaka et al. fail to teach this specific figure and fail to even discuss residency time. Whether or not a device is "intrinsically capable" of achieving the limitation of the claim through tweaking is irrelevant to establishing a prima facie case of obviousness, only what the reference actually teaches is relevant and these references fails to teach the limitation of claim 7.

Claim 8

Claim 8 defines residency of the vapor within the vaporizer as being at least 28 milliseconds. Neither Liebold or Hatanaka et al. teach or suggest this limitation.

Claim 13

Claim 13 defines that the step of passing the sterilant through the circuitous path comprises passing the sterilant through an orifice having a cross-sectional area no greater than 44.1% of a cross-sectional area of the circuitous path immediately upstream of the orifice. Neither Hatanaka et al. or Liebold contains an orifice much less one meeting the cross-sectional area limitation.

Claim 17 and 18

Claim 17 defines that at least 75% of the non-vaporizable components are removed from the sterilant prior to the step of passing the sterilant out of the vaporizer and claim 18 provides that substantially all of the non-vaporizable components are removed. Neither reference provides teachings with respect to non-vaporizable components.

F. The rejection of claims 9 to 12, 14, 16, 19 and 20 under 35 U.S.C. §103(a) over the Cummings et al. U.S. Patent No. 4,744,951, Hatanaka and Leibold.

As described earlier, there is no suggestion for combining the teachings of Hatanaka and Cummings et al. due to the fundamentally different nature of their processes. As the Examiner admits, Hatanaka et al. lack a flow restriction. The Examiner has made the fantastic allegation that one of skill in the art would be motivated to add a flow restriction to Cummings et al. "in

order to allow the apparatus to be used continuously instead of only intermittently, in a controlled manner without danger to the surrounding and personnel." The Examiner clearly has misunderstood Cummings et al. It is designed for intermittent operation, and due to the nature of its operation at extremely low pressures only batch processing is possible due to the problem of getting items into and out of the chamber. If the Examiner can figure out how to successfully combine such technology he should patent it. However, even if such a fantastic combination were made, it would fail to reach the claimed invention. None of the references teach collecting non-vaporizable components of the sterilant on surfaces forming the circuitous path.

Claim 12

Claim 12 refines the step of passing the sterilant through a circuitous path to include passing the sterilant through at least one portion in which an effective cross-sectional area of the portion increases by at least 89% thereby decreasing the speed of the sterilant passing therethrough. Hatanaka et al. lack this feature and the rejection of claim 12 lacks fails to point out where such feature lies in the reference. The Examiner has failed to establish a prima facie case of obviousness.

Claims 19 and 20

Claims 19 and 20 defines the sterilant as remaining within the vaporizer for at least 17 milliseconds, respectively. The cited references fail to teach these specific figures and fail to even discuss specific residency times. Whether or not the device of Liebold is "intrinsically capable" of achieving the limitation of the claim through tweaking is irrelevant to establishing a prima facie case of obviousness; only what the reference actually teaches is relevant and this reference fails to teach the limitation of either claim 19 or 20.

G. The rejection of claim 15 under 35 U.S.C. §103(a) over Cummings et al., Hatanaka, Leibold and the Feasey et al. US Patent No. 5,130,053.

There is no suggestion for combining the teachings of Hatanaka and Cummings et al. due to the fundamentally different nature of their processes. As the Examiner admits, Hatanaka et al. lack a flow restriction. The Examiner has made the fantastic allegation that one of skill in the art would be motivated to add a flow restriction to Cummings et al. "in order to allow the

apparatus to be used continuously instead of only intermittently, in a controlled manner without danger to the surrounding and personnel." The Examiner clearly has misunderstood Cummings et al. It is designed for intermittent operation, and due to the nature of its operation at extremely low pressures only batch processing is possible due to the problem of getting items into and out of the chamber. If the Examiner can figure out how to successfully combine such technology he should patent it. However, even if such a fantastic combination were made, it would fail to reach the claimed invention. None of the references teach collecting non-vaporizable components of the sterilant on surfaces forming the circuitous path. Feasey et al. teach one particular stabilizer, yet not that it can be collected in a vaporizer or even that it will fail to vaporize.

Conclusion

Applicants submit that the Examiner, while making a huge number of rejections, has in each case failed to establish a prima facie case of obviousness or anticipation. This failure stems from a misreading of the teachings of the references, in particular the Hatanaka et al. reference. Accordingly, Applicants request reversal of the rejections and allowance of the case.

Respectfully submitted,

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CLAIMS APPENDIX

1. A vaporizer for vaporizing a sterilant from its liquid phase in a vapor phase sterilization system having a pressure below atmospheric pressure, said vaporizer comprising:

an inlet whereby to receive the sterilant in its liquid phase;

an outlet whereby to discharge the sterilant in its vapor phase;

a circuitous path between the inlet and the outlet whereby to collect non-vaporizable ingredients of the sterilant; and

a flow restriction between the circuitous path and the outlet.

2. A vaporizer according to claim 1 wherein the circuitous path comprises a plurality of baffles.

3. A vaporizer according to claim 1 wherein the circuitous path comprises an inner tube positioned concentrically within an outer tube, the circuitous path including a first portion in a first direction between the inner tube and the outer tube and a second portion in a second opposite direction through the inner tube.

4. A vaporizer according to claim 1 wherein the circuitous path comprises at least one portion in which an effective cross-sectional area of the portion increases by at least 89% whereby to decrease the speed of the sterilant passing therethrough.

5. A vaporizer for vaporizing a sterilant from its liquid phase in a vapor phase sterilization system having a pressure below atmospheric pressure, said vaporizer comprising:

an inlet whereby to receive the sterilant in its liquid phase;

an outlet whereby to discharge the sterilant in its vapor phase;

a circuitous path between the inlet and the outlet whereby to collect non-vaporizable ingredients of the sterilant;

a flow restriction between the circuitous path and the outlet; and

wherein the flow restriction comprises an orifice having a cross-sectional area no greater than 44.1% of a cross-sectional area of the circuitous path immediately upstream of the orifice.

6. A vaporizer according to claim 1 wherein the circuitous path comprises at least two turns, each of which are at least 90 degrees.

7. A vaporizer according to claim 1 wherein the restriction can retain the vapor within the vaporizer for at least 17 milliseconds.

8. A vaporizer according to claim 7 wherein the restriction can retain the vapor within the vaporizer for at least 26 milliseconds.

9. A method of providing a vapor phase sterilant to a sterilization chamber comprising the steps of:

creating temperature and pressure conditions within a vaporizer sufficient to vaporize the sterilant said pressure condition comprising a pressure below atmospheric pressure;

admitting the sterilant, in its liquid phase, into the vaporizer and vaporizing the sterilant;

admitting no carrier gas into the vaporizer;

passing the sterilant through a circuitous path and collecting non-vaporizable components of the sterilant on surfaces forming the circuitous path;

then passing the sterilant, in its vapor phase, through a flow restriction; and

passing the sterilant, in its vapor phase, out of the vaporizer.

10. A method according to claim 9 wherein the step of passing the sterilant through a circuitous path comprises passing the sterilant past a plurality of baffles.

11. A method according to claim 9 wherein the step of passing the sterilant through the circuitous path comprises passing the sterilant in a first direction through an inner

tube positioned concentrically within an outer tube and in a second opposite direction between the inner tube and the outer tube.

12. A method according to claim 9 wherein the step of passing the sterilant through a circuitous path comprises passing the sterilant through at least one portion in which an effective cross-sectional area of the portion increases by at least 89% thereby decreasing the speed of the sterilant passing therethrough.

13. A method of providing a vapor phase sterilant to a sterilization chamber comprising the steps of:

creating temperature and pressure conditions within a vaporizer sufficient to vaporize the sterilant;

admitting the sterilant, in its liquid phase, into the vaporizer and vaporizing the sterilant;

passing the sterilant through a circuitous path and collecting non-vaporizable components of the sterilant on surfaces forming the circuitous path;

then passing the sterilant, in its vapor phase, through a flow restriction;

passing the sterilant, in its vapor phase, out of the vaporizer; and

wherein the step of passing the sterilant through the circuitous path comprises passing the sterilant through an orifice having a cross-sectional area no greater than 44.1% of a cross-sectional area of the circuitous path immediately upstream of the orifice.

14. A method according to claim 9 wherein the step of passing the sterilant through the circuitous path comprises having the sterilant make at least two turns, each of which are at least 90 degrees.

15. A method according to claim 9 wherein the non-vaporizable components comprise stabilizing compounds for the liquid phase of the sterilant.

16. A method according to claim 9 wherein the sterilant comprises hydrogen peroxide.

17. A method of providing a vapor phase sterilant to a sterilization chamber comprising the steps of:

creating temperature and pressure conditions within a vaporizer sufficient to vaporize the sterilant;

admitting the sterilant, in its liquid phase, into the vaporizer and vaporizing the sterilant;

passing the sterilant through a circuitous path and collecting non-vaporizable components of the sterilant on surfaces forming the circuitous path;

then passing the sterilant, in its vapor phase, through a flow restriction;

passing the sterilant, in its vapor phase, out of the vaporizer; and

wherein at least 75% of the non-vaporizable components are removed from the sterilant prior to the step of passing the sterilant out of the vaporizer.

19. A method according to claim 9 wherein the sterilant remains within the vaporizer for at least 17 milliseconds.

20. A method according to claim 19 wherein the sterilant remains within the vaporizer for at least 26 milliseconds.

EVIDENCE APPENDIX

[NONE]

RELATED APPEALS AND INTERFERENCES APPENDIX

[NONE]